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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,144	06/15/2001	Preben Nielsen	10033.200-US	7990

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/882,144	NIELSEN ET AL.	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The amendment and response file don 12/22/04 has been fully considered and entered into the application.
2. Claims 10, 15, 17-19 and 21 have been canceled, and claims 1, 5, 7 and 11 were amended, and new claims 22-24 have been added by the amendment filed on 12/22/04.
3. Claims 1-9, 11, 22-24 are currently pending and are being examined in this application.
4. The rejection of claims 1-9, 11 as being indefinite, for the reasons set forth in the previous office action have been withdrawn in view of amendments to the claims.
5. The art rejections of record over Rehman et al, Torkkeli et al, Stevens et al, and Borchert et al have been withdrawn in view of the amendment to the claims.

New Claim Rejections Necessitated by the Amendment

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-9, 11, 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description rejection.

The instant claim briefly recites a method for screening for compounds secreted by a micro-organism comprising: a) cultivating the microorganism to produce a supernatant or a supernatant including surface bound compounds of the microorganism which comprises at least

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2 secreted products, b) preparing a mixture of antibodies by immunizing an animal with the supernatant comprising at least 2 secreted products and isolating the mixture of antibodies formed in the animal, c) providing a gene library from the micro-organism, d) cloning the gene library into a suitable host organism; e) screening the clones for positive clones; f) screening positive clones for peptides or proteins having desired function.

The specification discloses methods for mining genomes for genes encoding proteins and peptides, including g enzymes that are secreted from microorganism. The instant invention further provides a novel screening method that makes it possible to screen the genome of a microorganism only once in order to identify all gene products secreted by the microorganism. Clones producing these secreted gene products may then easily and quickly be further screened for peptides or proteins having a desired function. The specification discloses the methods to produce supernatant culture of the microorganism, and use of the supernatant to immunize an animal to raise primary antibodies. The reference teaches methods of genomic DNA preparation, and screening the genomic DNA with primary antibodies (i.e., see page 27) (example 1). However, the specification has not disclosed the compounds identified by the claimed method from the genomic library. The specification example 1, has not identified peptides or proteins having desired function. The specification disclosure is hypothetical. The specification has not disclosed that the supernatant has at least two secretary products of the microorganism. The specification has not disclosed whether the primary antibodies obtained have mixture of antibodies. The specification description clearly does not provide an adequate representation regarding the open ended claimed method of the presently claimed invention.

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The specification has not disclosed the antibodies raised in an animal or at least two secreted products present in the supernatant, and then has not shown that the antibody mixture (antibodies to at least 2 supernatant products of microorganism) binds to cloned genes to identify the secreted compounds of the microorganism. And further if the genomic DNA library is prepared from the organism, the gene that encodes the secretory product may be present or silent, depending on the life phase or time the genomic library is prepared. Thus, the genomic DNA library need to be pre-screened to make sure that the genomic DNA library has genes that encode the protein. Thus, using the claimed method at least 2 compounds secreted by the microorganism is not identified. The specification has no support to identify at least 2 secretory products of microorganism using the claimed method.

Further, the compounds obtained from the positive clones require further testing or screening to identify the compounds have desired function. Thus, the initial screening may not result in compounds of known function. The specification discloses that bacterial enzymes as the compounds identified by the claimed method, however none of the working examples show the at least 2 bacterial enzymes identified by the claimed method.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., > Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003);< Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention

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involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1405 (1997), quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in University of California v. Eli Lilly defined the invention by function of the claimed DNA (encoding insulin)].

This holding would be deemed to be applicable to the method in which the compounds are identified, which requires a representative sample of compounds and/or a showing of sufficient identifying characteristics of the compounds to demonstrate possession of the claimed generic(s).

In the present instance, the claimed invention contains no identifying characteristics regarding the at least two secretary products identified by the claimed method.

Additionally, the narrow scope of examples directed to generic method are clearly not representative of the scope of at least two secretary products of supernatant of a microorganism identified by the claimed method.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "the secreted product" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the donor organism". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Rehman et al (Molecular and Biochemical Parasitology, 97 (1998) 55-68).

The instant claim briefly recites a method for screening for compounds secreted by an organism comprising: a) cultivating the organism to produce a supernatant or a supernatant including surface bound compounds of the organism which comprises at least 2 secreted products, b) preparing a mixture of antibodies by immunizing an animal with the supernatant comprising at least 2 secreted products and isolating the mixture of antibodies formed in the animal, c) providing a gene library from the organism, d) cloning the gene library into a suitable host organism; e) screening the clones for positive clones; f) screening positive clones for peptides or proteins having desired function.

Rehman et al teach methods for isolation of secreted protein genes from the gut of the parasitic nematode (refers to the organism or the donor organism of the instant claims). The reference teaches that polyclonal antisera (refers to instant claim step a)) made against the

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secreted proteins (at least 2 secreted products of the instant claims) were used to screen expression cDNA libraries made either from adult worm gut or whole worm (refers to the step c), 'gene library from the donor organism' of the instant claims) (i.e., see the abstract). The reference teaches that the genes identified encode secreted proteins from the gut, including cysteine protease, a zinc metallopeptidase (i.e., see the abstract). The reference teaches methods for raising antibodies to *H. contortus* antigens (i.e., see page 56, right column). The reference teaches methods for constructing cDNA libraries from either the whole gut of adult female *H. contortus* or whole worms. The reference teaches that the cDNA was cloned into λ Zap II vector (refers to instant claim step c), and the λ vectors refers to the host organism). Thus, the antibodies raised for antigens of same organism as the source of the cDNA. The reference *H. contortus* refers to the donor organism of the instant claims. The reference teaches methods for immunoscreening the cDNA library using the antibodies to the proteins, and positive plaques (refers to the positive clones of the instant claims) were purified by four successive rounds of screening (i.e., see page 57). The reference teaches that 36 clones were identified from the *H. contortus* gut cDNA library that was identified by the antisera to the antigens. The reference teaches that the encoded gut proteins are likely to be involved in nutrient digestion (refers to the desired functionality). The reference clearly anticipates the claimed method.

Response to Arguments

12. Applicant's arguments with respect to claims 1-9, 11, 22-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. No claims are allowed.

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14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

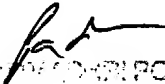
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

19 March 2005


PADMASHRI PONNALURI
PRIMARY EXAMINER